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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/668,640	09/23/2003	Harinath B. Bathina	34085	2066

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HOVEY WILLIAMS LLP
Suite 400
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EXAMINER

BROOKS, KRISTIE LATRICE

ART UNIT	PAPER NUMBER
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1616

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07/27/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/668,640	Applicant(s) BATHINA ET AL.	
	Examiner Kristie L. Brooks	Art Unit 1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 September 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-38 is/are pending in the application.
- 4a) Of the above claim(s) 33-38 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-32 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>12/22/03; 12/15/03</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of Application

1. Claims 1-38 are pending.
2. Applicant's election without traverse of January 8, 2007 in the reply filed on December 5, 2006 is acknowledged.
3. The election of species of aliphatic and aromatic hydrocarbons hydrocarbon resins in claim 2, ketones in claim 8 and linear or branched chain fatty acids in claim 10, without traverse is acknowledged.
4. Claims 1-32 are the claims drawn to the elected species and are presented for examination and claims 33-38 are withdrawn from consideration as being drawn to the nonelected subject matter.

Specification

5. The disclosure is objected to because of the following informalities: The use of the trademark Wingtack®, Piccovar®, Priplast®, NovaRes® has been noted in this application. It should be capitalized or accompanied by a ® or ™ symbol wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Claim Rejections - 35 USC § 112, 2nd

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 21- 22 and 31-32 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 21-22 are indefinite due to the phrase "at least about," which simultaneously refers to a broad range and a narrower range. In the instant case, for example the conflicting phrase "at least about 15%" is unclear as to whether it is at least 15 %, in which the range cannot fall below 15 %, or about 15%, in which the range can include a value below 15 %. Therefore, it would be unclear to a skilled artisan, which range Applicants are claiming.

Claims 31-32 refer to the composition of claim 46. Since there is no claim 46 present in the application, it is indefinite.

Double Patenting

8. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140

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F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

9. Claims 1, 4-15, 18-22, and 25-32 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 and 3-16, 20, and 23-25 of U.S. Patent No. 6,030,633.

Although the conflicting claims are not identical, they are not patentably distinct from each other because they both encompass a film forming skin protectant composition comprising polyether polyurethane and a tackifier resin. Claims 1, 4-15, 18-22, and 25-32 of the instant invention are drawn to a film-forming skin protectant composition comprising polyether polyurethane and a tackifier resin. Claims 1 and 3-16, 20, and 23-25 of U.S. Patent No. 6,030,633 are drawn to a film-forming skin protectant composition comprising polyether polyurethane, benzoin gum (tackifier resin), and nitrocellulose (tackifier resin). The instant invention differs from the cited patent by reciting the tackifier resin is a resinous material other than gum. However, that does not exclude additional resinous material that is a gum resin from being present in the film-

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forming skin protectant composition. Therefore, the film-forming skin protectant composition as claimed in U.S. Patent No. 6,030,633 is rendered obvious by the instant invention.

10. Claims 1-3, 6-10, 21-24, and 26-31 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 3-6, 9-10 and 21 of U.S. Patent No. 5,942,239 in view of Klofta (US Pub. No. 2004/0191279).

Claims 1-3, 6-10, 21-24, and 26-31 of the instant invention are drawn to a film-forming skin protectant composition comprising polyether polyurethane and a tackifier resin.

Klofta teaches a skin care composition which provide enhanced transfer of the composition to the skin and increased adhesion to the skin comprising a) 5% to about 95% by weight of an emollient, b) from about 10% to about 95% by weight of a tackifying agent, and c) optionally from about 1% to about 95% of an immobilizing agent (see the entire article, especially the abstract). Preferred materials used as tackifiers include rosin resins such as those derived from gum rosin, hydrocarbon resins such as the C-5 aliphatic resins, the C-9 aromatic resins and mixtures thereof (see the entire article, especially page 3-4 paragraph [0032]).

Although the conflicting claims are not identical, they are not patentably distinct from each other because they both encompass a film forming composition comprising

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polyether polyurethane and a tackifier resin. The instant invention differs from the cited patent by reciting the tackifier resin is a resinous material other than gum. However, that does not exclude additional resinous material that is a gum resin from being present in the composition. Furthermore, it is well known in the art that tackifier resins are used to increase adhesive properties in compositions to be applied to the skin as suggested by Kiofta et al. and in the absence of unexpected results, it would have been obvious to one of ordinary skill in the art to employ any tackifier resin, such as a gum rosin (i.e. benzoin gum), C-5 aliphatic hydrocarbon resins, C-9 aromatic hydrocarbon resins or mixtures thereof, into the compositions. Therefore, both applications are directed to similar subject matter wherein the composition comprises polyether polyurethane and a tackifier resin.

Claim Rejections - 35 USC § 102

11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

12. Claims 1, 12 and 21-22 are rejected under 35 U.S.C. 102(b) as being anticipated by Hemling et al. (US 6,030,633).

Note: For the purposes of searching for and applying prior art under 35 U.S.C. 102 and 103, absent a clear indication in the specification or claims of what constitutes

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a material change to the basic and novel characteristics of the invention, "consisting essentially of" will be construed as equivalent to "comprising." If applicant contends that additional materials of the prior art are excluded by the recitation of "consisting essential of", applicant has the burden of showing that the introduction of additional components would materially change the characteristics of applicant invention. See MPEP 2111.03.

Hemling et al. teach an improved film forming skin protectant compositions capable of forming an elastic film when applied to the skin, having a particular utility as barrier teat dips, for protecting cows against mastitis, comprising a film forming component comprising a mixture of polyether polyurethane and benzoin gum (a tackifier resin) and nitrocellulose (a tackifier resin) dispersed in a carrier (see the entire article, especially the abstract). The overall film-forming component is present at a level of about 5-50%, where the polyether polyurethane is used at a level of 5-25%, benzoin gum is present at a level of 2-20% and nitrocellulose is present at a level of 0.2-15% by weight (see the entire article, especially column 2 lines 12-14 and 24-31). The composition having a retention time of about 10% and 15 % greater as compared to an otherwise identical composition including only benzoin gum and no other tackifier resin would be an inherent property of the formulation taught by Hemling et al. because the composition is composed of the same ingredients.

Claim Rejections - 35 USC § 103

13. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

14. Claims 1-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hemling et al. (US 6,030,633) in view of Klofta (US Pub No. 2004/0191279).

Note: For the purposes of searching for and applying prior art under 35 U.S.C. 102 and 103, absent a clear indication in the specification or claims of what constitutes a material change to the basic and novel characteristics of the invention, "consisting essentially of" will be construed as equivalent to "comprising." If applicant contends that additional materials of the prior art are excluded by the recitation of "consisting essential

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of", applicant has the burden of showing that the introduction of additional components would materially change the characteristics of applicant invention. See MPEP 2111.03.

Applicant claims a film forming skin protectant composition comprising polyether polyurethane dispersed in a carrier and a tackifier resin.

Determination of the scope and content of the prior art

(MPEP 2141.01)

Hemling et al. teach an improved film-forming skin protectant compositions that are capable of forming a long lasting elastic barrier film when applied to the skin (see the entire article, especially the abstract). The compositions include a film forming component (preferably a mixture of polyether polyurethane and benzoin gum) dispersed in a carrier and a quantity of nitrocellulose in an amount sufficient to increase the time of adherence of the composition to the skin (see the entire article, especially the abstract). Benzoin gum has been found to significantly increase the adhesion time of protectant compositions (see the entire article, especially column 1 lines 43-45). The film-forming component preferably includes polyether polyurethane used at a level from about 5-25 % by weight and benzoin gum being present at a level of about 2-20% by weight (see the entire article, especially column 2 lines 24-31). The carrier portion is preferably a solvent selected from THF, toluene, acetone, and the C₁-C₄ ethers, ketones and alcohols (see the entire article, especially column 2 lines 24-32, 42-46). Nitrocellulose is present at a level from about 0.2 to 15 % by weight in the film-forming protectant

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compositions (see the entire article, especially column 2 lines 12-16). The compositions may also include a germicidal agent or combinations of germicides dispersed in the carrier, which may be present at a level from 0.01-2% by weight (see the entire article, especially column 2 lines 49-52). The germicidal agent may be selected from a wide variety of agents such as linear or branched chain fatty acids (i.e. octanoic acid, nonanoic acid and decanoic acid) (see the entire article, especially column 2 lines 53-55). Dyes such as D&C red 19 and solvent yellow 43 may also be added to the skin protectant compositions of the invention in order to improve the visualization of the barrier film on the skin area being treated (see the entire article, especially column 3 lines 1-8). The compositions of the invention should have a viscosity of about 50-2000 cPs (see the entire article, especially column 3 lines 14-16).

Klofta teaches a skin care composition which provide enhanced transfer of the composition to the skin and increased adhesion to the skin comprising a) 5% to about 95% by weight of an emollient, b) from about 10% to about 95% by weight of a tackifying agent, and c) optionally from about 1% to about 95% of an immobilizing agent (see the entire article, especially the abstract). Preferred materials used as tackifiers include rosin resins such as those derived from gum rosin, hydrocarbon resins such as the C-5 aliphatic resins, the C-9 aromatic resins and mixtures thereof (see the entire article, especially page 3-4 paragraph [0032]).

Ascertainment of the difference between the prior art and the claims

(MPEP 2141.02)

Hemling et al. do not teach said tackifier resin being aliphatic and aromatic hydrocarbon resins whereas the Applicant claims a film forming skin protectant composition comprising a film forming component and a tackifier resin, wherein said tackifier resin is a aliphatic and aromatic hydrocarbon resin.

Finding of prima facie obviousness

Rational and Motivation (MPEP 2142-2143)

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to make a film forming skin protectant composition comprising a film forming component and a tackifier resin, wherein said tackifier resin is a aliphatic and aromatic hydrocarbon resin.

One of ordinary skill in the art would have been motivated to do this because Hemling et al. suggest compositions comprising a film forming component (preferably a mixture of polyether polyurethane and benzoin gum) dispersed in a carrier and nitrocellulose. The film-forming component preferably includes polyether polyurethane used at a level from about 5-25 % by weight and benzoin gum being present at a level of about 2-20% by weight. The carrier portion is preferably a solvent selected from THF, toluene, acetone, and the C₁-C₄ ethers, ketones and alcohols. Nitrocellulose is present at a level from about 0.2 to 15 % by weight in the film-forming protectant compositions. The compositions may also include a germicidal agent or combinations of germicides

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dispersed in the carrier, which may be present at a level from 0.01-2% by weight. The germicidal agent may be selected from a wide variety of agents such as linear or branched chain fatty acids. Hemling et al. do not suggest the use of tackifier resins such as aliphatic and aromatic hydrocarbon resins. However, it is well known in the art that tackifier resins are used to increase adhesive properties in compositions to be applied to the skin as suggested by Klofta et al. and in the absence of unexpected results, one of ordinary skill in the art would have employed any tackifier resin, such as a gum rosin (i.e. a benzoin gum), C-5 aliphatic hydrocarbon resins, C-9 aromatic hydrocarbon resins or mixtures thereof, into the compositions. Therefore, the claimed invention would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made because the prior art is fairly suggestive of the claimed invention.

Conclusion

15. No claims are allowed.

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kristie L. Brooks whose telephone number is (571) 272-9072. The examiner can normally be reached on M-F 8:30am-6:00pm Est..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann R. Richter can be reached on (571) 272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

KB

Paul H. Landon
Primary Examiner
AU 1616